K010950

JUN 2 7 2001

Attachment 6

510(k) SUMMARY FOR ACUSON CORPORATION'S

CYPRESS ULTRASOUND SYSTEM

Sponsor:

Acuson Corporation
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Mountain View, California 94039-7303
Telephone: (650) 969-9112
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Contact Person:

Gladys May-Cooper
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or

Howard M. Holstein, Esq.
Hogan & Hartson, LLP
555 Thirteenth Street, N.W.
Washington, DC 20004
Tel: (202) 637-5813
Fax: (202) 637-5910

Submission Date:

March 29, 2001

Device Name: Acuson Cypress System

Classification:

Ultrasonic Pulsed Doppler Imaging System (90 IYN), class II (21 C.F.R. §892.1550)

Predicate Devices:

1. Acuson Cypress Ultrasound System (K982800 and K991872)
2. Acuson Aspen™ Ultrasound System (K934915, K991805)
3. Acuson Sequoia™ Ultrasound System (K935595 and K973767)
4. Acuson AcuNav Diagnostic Ultrasound Catheter (K992631)

Device Description:

The Acuson Cypress Ultrasound System ("Cypress") is an ultrasound imaging platform which is designed for use with a variety of internal and external transducers. The purpose of this submission is to obtain clearance for a minor modification to the system to support use of an additional transducer, the AcuNav™ Diagnostic Ultrasound Catheter ("AcuNav"), which is a single-use, disposable, steerable, ultrasound-tipped catheter device that applies ultrasound energy directly within the vasculature and/or the right heart. This transducer has previously been cleared for use with the company's Aspen™ Ultrasound System ("Aspen") and Sequoia™ Ultrasound System ("Sequoia") imaging platforms (K992631).

Intended Use:

The Acuson Cypress System is generally intended for use in diagnostic ultrasound imaging. When used in conjunction with the AcuNav, the device is intended for use in intravascular or intracardiac imaging, and is specifically indicated for use in visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart, as well as hemodynamic monitoring.

Substantial Equivalence:

Acuson's Cypress System is substantially similar to the predicates with respect to intended use/indications for use, principles of operation, and technological characteristics. The

only difference in the intended use/indications for use of the modified Cypress System compared to the previously cleared Cypress System is its additional indication for use in intracardiac and intravascular imaging when used in conjunction with the AcuNav Catheter. However, this indication has already been cleared for use with the company's other ultrasound platforms, the Aspen and the Sequoia, which are substantially similar to the Cypress System, and is substantially similar to the previously cleared indication for use of the Cypress in intraoperative cardiac imaging.

The technological features of the Cypress System also are substantially similar to the predicates. The minor hardware and software modifications to the Cypress System required to support use of the AcuNav are substantially similar to the software modifications to the Aspen and Sequoia systems required to support use of the AcuNav and, therefore, do not raise any new questions of safety and effectiveness. The other minor differences in operating frequency and image enhancement features also do not raise any new questions of safety or effectiveness. Moreover, appropriate validation testing has been conducted to ensure the quality of the images produced by the Cypress System when used in conjunction with the AcuNav. Therefore, the modified Cypress System is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2001

Acuson Corporation
c/o Mr. Howard M. Holstein
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth St., N.W.
Washington, D.C. 200004-1109

Re: K010950
Trade Name: Cypress Ultrasound System with AcuNav™ Diagnostic Ultrasound Catheter
Regulatory Class: II
Product Code: IYO/ 892.1560
Dated: March 29, 2001
Received: March 29, 2001

Dear Mr. Holstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the AcuNav catheter transducer intended for use with the Cypress Ultrasound System, as described in your premarket notification.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further

announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Robert Phillips, Ph.D., at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K010950

Attachment 7

STATEMENT OF INDICATIONS FOR USE

Intended Use

With the Acuson AcuNav Diagnostic Ultrasound Catheter the Cypress is specifically indicated for use in visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart, as well as measurement of blood flow. The AcuNav Diagnostic Ultrasound Catheter is a disposable, single-use ultrasound-tipped catheter device which is used directly within the venous vasculature and/or right heart for intravascular or intracardiac ultrasound imaging. It is intended for right heart use only.

Diagnostic Ultrasound Indications for Use Form
For
Cypress Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	B	M	PWD	CWD	Color Doppler	Other Harmonic Imaging
Fetal	P	P	P	P	P	P
Abdominal	P	P	P	P	P	P
Intra-operative (Cardiac)	P	P	P	P	P	P
Pediatric	P	P	P	P	P	P
Neonatal Cephalic	P	P	P	P	P	P
Cardiac (Adult)	P	P	P	P	P	P
Cardiac (Pediatric)	P	P	P	P	P	P
Trans-esophageal	P	P	P	P	P	P
Intra-Luminal	N	N	N	N	N	
Peripheral Vascular	P	P	P	P	P	P
Other (Intra-Cardiac)	N	N	N	N	N	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

The Cypress Ultrasound System does not provide combined modes (where more than one scanning mode is active simultaneously).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Device Use ✓

(Per 21 CFR 801.109)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010950